UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,034	02/21/2002	William Hildebrand	6680.040	9571

7590 05/03/2004	**EXAMINER**
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ART UNIT	PAPER NUMBER
1631	

9400 North Broadway
Oklahoma City, OK 73114

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/082,034	HILDEBRAND ET AL.
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/5/03*.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-11* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-11* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date *07182003, 12052003*.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Applicants' election without traverse of Group III (claims 3-5), filed 12/5/03, is acknowledged. Cancelled claims 1-2 and new claims 6-11 are acknowledged.

The information disclosure statements, filed 7/18/03 and 12/5/03, have been fully considered.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, page 41 (second paragraph), 50 (line 23), 51 (lines 4, 6, 14), 52 (last 2 lines), 56 (lines 15 and 16), 66 (line 3), and Figures 5, 6, 8, and 10. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because SEQ ID Nos cited along with each sequence in the specification or Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy, or CD-ROM for the specification, statements under 37 CFR § 1.821 (f) and (g), if there is a need to list additional sequences in the sequence listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Claims herein under examination are 3-11.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other

form of browser-executable code, such as on page 2, line 19; page 79, lines 4-5; page 87, line 23;

and in Figure 12. Applicant is required to delete the embedded hyperlink and/or other form of

browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 8 is objected to because of the following minor informality: "soluable" on line 3 is

misspelled. Appropriate correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
> matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions
> and requirements of this title.

Claims 3-11 are rejected under 35 U.S.C. 101 because the claims are directed to non-

statutory subject matter.

These claims are directed to a database which is non-functional descriptive material that

includes a compilation or mere arrangement of data (see MPEP § 2106 IV(B)(1) and § 2106

IV(B)(1)(b)). MPEP § 2106 IV(B)(1) states the following regarding non-statutory subject

matter:

> Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir.
> 1994) (claim to data structure stored on a computer readable medium that increases
> computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d

at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance.

MPEP § 2106 IV(B)(1)(b) states the following regarding non-statutory subject matter:

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

Claims 3-11 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, claims 3-11 encompass a computer-related invention (database) that appears to lack any physical result performed outside of a computer.

As stated in MPEP § 2106, (IV)(B)(2)(b), to be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in MPEP § 2106 (IV)(B)(2)(b)(i)), or (B) be

limited to a practical application within the technological arts (discussed in MPEP § 2106

(IV)(B)(2)(b)(ii)).

As stated in MPEP § 2106 (IV)(B)(2)(b)(i), the independent physical acts may be post- or

pre-computer processing activity as described below:

> A process is statutory if it requires physical acts to be performed outside the computer
> independent of and following the steps to be performed by a programmed computer,
> where those acts involve the manipulation of tangible physical objects and result in the
> object having a different physical attribute or structure. Diamond v. Diehr, 450 U.S. at
> 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process
> steps that result in a physical transformation outside the computer (beyond merely
> conveying the direct result of the computer operation), the claim is clearly statutory.

> Another statutory process is one that requires the measurements of physical objects or
> activities to be transformed outside of the computer into computer data (In re Gelnovatch,
> 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not
> measure physical phenomenon); Arrhythmia, 958 F.2d at 1056, 22 USPQ2d at 1036),
> where the data comprises signals corresponding to physical objects or activities external
> to the computer system, and where the process causes a physical transformation of the
> signals which are intangible representations of the physical objects or activities. Schrader,
> 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval Arrhythmia, 958 F.2d at 1058-
> 59, 22 USPQ2d at 1037-38; Abele, 684 F.2d at 909, 214 USPQ at 688; In re Taner, 681
> F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

As stated in MPEP § 2106 (IV)(B)(2)(b)(ii), the computer-related process may be limited

to a practical application in the technological arts as described below:

> There is always some form of physical transformation within a computer because a
> computer acts on signals and transforms them during its operation and changes the state
> of its components during the execution of a process. Even though such a physical
> transformation occurs within a computer, such activity is not determinative of whether
> the process is statutory because such transformation alone does not distinguish a statutory
> computer process from a nonstatutory computer process. What is determinative is not
> how the computer performs the process, but what the computer does to achieve a
> practical application. See Arrhythmia, 958 F.2d at 1057, 22 USPQ2d at 1036.

Claims 3-11 do not fulfill either of these statutory requirements and are therefore rejected

under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims 3-11 are rejected under 35 U.S.C. 101 because the claims are directed to non-

statutory subject matter. As written, the claims appear to be directed to a database that is

involved in the manipulation of numbers, abstract concepts or ideas, or signals representing any

of the foregoing.

As stated in MPEP § 2106, (IV)(B)(1), if the "acts" of a claimed process manipulate only

numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not

being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59.

Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers

into another set of numbers, does not manipulate appropriate subject matter and thus cannot

constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

> – consist solely of mathematical operations without some claimed practical application
> (i.e., executing a "mathematical algorithm"); or
> – simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30
> USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31
> USPQ2d at 1759), without some claimed practical application.

Claims 3-11 do not fulfill any of these statutory requirements and are therefore rejected

under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 3-11 are vague and indefinite due to the unclarity of citing an abbreviation, such as HLA. Correction is suggested by amending in of the full name in parentheses.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Schafer et al. (Vaccine, Vol. 16, No. 19, 1998, pages 1880-1884).

Schafer et al. disclose a computer-driven analysis of sequences to permit the identification of peptides that bind to major histocompatibility (MHC) molecules (MHC ligands) such as human leucocyte antigens (HLA) ligands (abstract and page 1883, col. 1, second and third paragraphs). Schafer et al. disclose using a spreadsheet (database) of putative ligands (page

1881, col. 2, third paragraph) and show a list of ligands after binding assays with the HLA (Table

1). Schafer et al. disclose performing in vitro peptide binding assays to assess peptide binding

and stability to HLA-B27 and HLA-A2 (page 1881, col. 2, fourth paragraph). Schafer et al.

disclose the isolates of ligands as well as their resulting sequences (Table 1, columns 2 and 9).

Schafer et al. disclose estimated binding probabilities and highest fold changes in Table 1

(columns 3-6) which represent a linear manipulation of the HLA ligand data, as stated in instant

claim 4. Schafer et al. disclose using EpiMatrix, a predictive algorithm to identify MHC ligands

(page 1880, col. 2, first paragraph), as stated in instant claim 5. The spreadsheet and computer-

driven analysis, as well as binding results described above represent a memory media that stores

the data structure of HLA ligand data, as stated in instant claim 6.

Thus, Schafer et al. anticipate the limitations in claims 3-7.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the

claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims

was commonly owned at the time any inventions covered therein were made absent any evidence

to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35

U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al.

(Vaccine, Vol. 16, No. 19, 1998, pages 1880-1884) in view of Thalhammer-Reyero (P/N

5,980,096).

Schafer et al. describe a computer-driven analysis of sequences to permit the

identification of peptides that bind to major histocompatibility (MHC) molecules (MHC ligands)

such as human leucocyte antigens (HLA) ligands (abstract and page 1883, col. 1, second and

third paragraphs). Schafer et al. describe using a spreadsheet (database) of putative ligands (page

1881, col. 2, third paragraph) and show a list of ligands after binding assays with the HLA (Table

1). Schafer et al. describe performing in vitro peptide binding assays to assess peptide binding

and stability to HLA-B27 and HLA-A2 (page 1881, col. 2, fourth paragraph). Schafer et al.

describe the isolates of ligands as well as their resulting sequences (Table 1, columns 2 and 9).

Schafer et al. describe estimated binding probabilities and highest fold changes in Table 1

(columns 3-6) which represent linear manipulations of the HLA ligand data, as stated in instant

claim 4. Schafer et al. describe using EpiMatrix, a predictive algorithm to identify MHC ligands

(page 1880, col. 2, first paragraph), as stated in instant claim 5. The spreadsheet and computer-

driven analysis, as well as binding results described above represent a memory media that stores

the data structure of HLA ligand data, as stated in instant claim 6. Schafer et al. do not describe

instructions for receiving a soluble HLA ligand data request from a requestor, receiving and

returning a match request, as stated in instant claim 8. Schafer et al. do not describe receiving a

request from a remote connection, as stated in instant claim 9.

Thalhammer-Reyero describes an integrated computer-based interface, methods, and

systems for the development and deployment of graphical information storage (databases) and

retrieval (abstract and col. 4, lines 65-67). Thalhammer-Reyero describes information and

mathematical models in the form of tables wherein various forms of information can be extracted

from predefined queries (abstract). Thalhammer-Reyero describes a "user" (requestor) as a

person that extracts accumulated knowledge and runs simulations (col. 13, lines 47-49).

Thalhammer-Reyero describes providing data including DNA and ligands as well as processes

and interactions (col. 15, lines 17-34). Thalhammer-Reyero describe a ligand database as seen in

Figure 10. Thalhammer-Reyero describes a request, finding matches, and then displaying the list

as output (col. 99, lines 36-50). Thalhammer-Reyero describes databases (col. 2, line 17) and

using models for prediction and hypothesis formation (col. 3, lines 1-14). Thalhammer-Reyero

describes knowledge-based and model-based systems (col. 3, line 36) including inference

engines, simulators, user-interfaces to search for and locate information which can be saved and

shared with networked remote CPUs or terminals (col. 4, lines 31-56).

Schafer et al. state the need for an effective vaccine against HIV-1 that takes into

consideration the variability of HIV strains remains urgent (page 1880, col. 1, first paragraph).

Schafer et al. state that EpiMatrix and other computer-driven algorithms that predict MHC

ligands place the prospective design of a novel HIV-1 vaccine within reach. One of ordinary

skill in the art would have been motivated to use a system can be used by scientists as a new

form of interactive research tool to integrate information and data that can be modified and its

parameters adjusted as new information and data pertinent to the system under study becomes

available (col. 10, lines 40-45), as stated by Thalhammer-Reyero, in HIV research in order to

utilize computer-driven methods of identifying potential leads for HIV-1 vaccine development

and put such development within reach (page 1883, col. 2, second paragraph). Therefore, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to

use the interactive system using remote requestors, as stated by Thalhammer-Reyero, in the

predictive algorithm and HLA ligand database, as stated by Schafer et al., in order to come up

with prospectively designed vaccines to variable HIV-1 strains (Schafer et al., page 1880, col. 1,

first paragraph and col. 2, second paragraph) where the information is constantly evolving

(Thalhammer-Reyero).

Thus, Schafer et al., in view of Thalhammer-Reyero, motivate claims 3-11.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile

transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform with the notices published in the

Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703)

872-9306.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The

examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be

directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-

0549.

4/14/04

ARDIN H. MARSCHEL   4/29/04
PRIMARY EXAMINER